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TITLE: Second CIMIT/TATRC Symposium on Plug-and-Play (PNP) Interoperability Medical Devices in the ORF of the Future

PRINCIPAL INVESTIGATOR: Julian M. Goldman, M.D.

CONTRACTING ORGANIZATION: Massachusetts General Hospital
Boston, Massachusetts 02114-2554

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Fort Detrick, Maryland 21702-5012

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Julian M. Goldman, M.D.

E-Mail: jmgoldman@partners.org

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Massachusetts General Hospital
Boston, Massachusetts 02114-2554

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Fort Detrick, Maryland 21702-5012

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14. ABSTRACT
Funding was requested for a symposium to continue the process of defining technical and clinical requirements for a Medical Device "Plug-and-Play" (MD PnP) interoperability standardization framework for medical devices in the Operating Room of the Future and across the continuum of healthcare. The two-day symposium convened a group of 85 medical device producers, clinical users, biomedical engineers, governmental regulators (the FDA), and standards experts to 1) educate new participants in the issues and barriers to implementing MD PnP interoperability; 2) provide a forum to discuss relevant technology, the regulatory picture, and the refinement of clinical requirements; 3) elicit the participants' contributions to defining the vision and role of the MD PnP Lab, and 4) explore the benefits of broadening the initial OR of the Future-focused "ORF PnP" initiative to encompass the broader healthcare spectrum as "MD PnP". Significant progress was made in the areas of clinical requirements for MD PnP and development of a vision and plan for a PnP "sandbox" laboratory. Follow-on activities included expanding the network of collaborators and stakeholders, presenting meeting results and program progress in multiple venues, leading to further connections and collaborations, and concrete progress on clinical use case scenarios and implementing the PnP Lab.

15. SUBJECT TERMS
Medical device, plug-and-play, interoperability, patient safety, device control, operating room, health care

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Report on ORF PnP Symposium Held on June 6-7, 2005
Award Number W81XWH-05-2-0070

Introduction

Healthcare – especially the operating room environment – does not have standardized medical device control and communication systems. As a result, many self-evident improvements – such as seamless data communication, medical device integration, remote device actuation, and distributed closed-loop control systems – have been precluded, and safety and economic benefits have not been realized. Funding was sought for a symposium to continue the process of defining technical and clinical requirements for a Medical Device "Plug-and-Play" (MD PnP) interoperability standardization framework for medical devices in the Operating Room of the Future (ORF) and across the continuum of healthcare. To effectively define these requirements and set an agenda for standards development required convening a group of medical device producers, clinical users, biomedical engineers, governmental regulators (including the FDA), and standards experts. The two-day symposium was organized to 1) educate new participants in the issues and barriers to implementing MD PnP interoperability; 2) provide a forum to discuss relevant technology, the regulatory picture, and the refinement of clinical requirements; 3) elicit the participants' contributions to defining the vision and role of the MD PnP Lab, and 4) explore the benefits of broadening the initial OR of the Future-focused "ORF PnP" initiative to encompass the broader healthcare spectrum as "MD PnP".

Body of Report

The second MD PnP Symposium jointly sponsored by TATRC and CIMIT was held on June 6-7 2005 at CIMIT in Cambridge, MA. A group of 85 clinical and technical thought leaders – medical device producers, clinical users, biomedical engineers, governmental regulators, and standards experts – participated, including 40 clinical and academic device "users" (9 from Kaiser Permanente and 6 from New York Presbyterian), 40 industry participants from 21 companies (11 of which were new to PnP), 2 from engineering societies (IEEE and ACCE), 2 FDA staff, and a TATRC representative). This symposium brought together these diverse groups for the third time, and with each meeting the dialogue has moved to a higher level of participation and mutual understanding of program goals and strategy. Of the 85 participants, 46 were new to the program, while 39 had attended a previous meeting (in May or November 2004).

As in the previous two MD PnP plenary meetings, the group discussed a range of topics regarding the issues, challenges, and potential benefits of achieving medical device interoperability, and expanded that discussion to encompass other healthcare environments such as home health care and ambulatory practice. The agenda (Appendix A) included speakers from related academic and laboratory programs; an update on the work with the FDA on a new regulatory paradigm; breakout sessions to discuss high level clinical requirements and to articulate an initial plan for the MD PnP Lab; a demonstration of the potential of plug-and-play technology for medical devices, based on the LiveData, Inc, "RTI" integrated display system; two other lab technology demonstrations; and a discussion of potential system architecture solutions. With the focus on clinical requirements and planning the lab, this meeting moved the program from the conceptualizing phase to the planning and working phase.

Meeting highlights included:

- Broadening of the stakeholder community, while preserving existing interest

- Multiple attendees from new companies (including Cisco, Lockheed Martin, Olympus, Stryker, Smith & Nephew, and others) as well as from those already involved (including Draeger, GE Healthcare, Philips, LiveData, Datascope, IBM, and others)
- Consolidation and categorization of the high-level clinical requirements collected to date
- Articulation of issues and considerations for planning an MD PnP "sandbox" laboratory to evaluate proposed interoperability solutions and implement clinical use cases
- Preliminary definition of the value proposition for medical device interoperability
- Initial discussion of a framework for future organization and funding of the program
- Identification of paths for seeking and evaluating potential system architecture solutions
- Strong consensus for the PI to move the program forward to the next phase

Talks given at the symposium were videotaped and subsequently made available as streaming video on the MD PnP (www.mdpnp.org) and CIMIT web sites (www.cimit.org). There have been almost 600 hits on these pages since they became available in February. Newcomers to the PnP program are referred to these talks, as well as those from the May 2004 TATRC-sponsored kick-off symposium, as valuable background.

As with the kick-off symposium in May 2004, this symposium led to a series of related follow-up activities that have continued to broaden support for the MD PnP vision and goals. These have included ongoing work on refining clinical requirements into use cases, progress towards getting a PnP lab up and running, efforts to educate additional organizations in the value of medical device PnP, visits to other DoD-supported programs working on related efforts, and meetings with the Office of the National Coordinator for Health IT.

The high level clinical requirements that we collected at a series of focus group sessions held at medical societies in FY05 were summarized with the help of a clinical engineer from Kaiser Permanente and presented at the June symposium in a breakout group, where they were further discussed and refined. In August, IBM hosted a two-day small group working meeting to organize clinical scenarios in an FDA-recommended framework. Participants in this meeting included Kaiser Permanente and the FDA, three IBM engineers and program managers, and the MD PnP PI and Project Manager. The session resulted in a set of clinical requirements that will help to inform engineering specifications. These results are being further reviewed, vetted with clinical groups, and extended to include additional requirements.

Subsequent to the June symposium, we developed a more complete articulation of the plan for the MD PnP Lab and the various roles it will play in advancing the goal of achieving MD PnP interoperability. A significant number of companies (Draeger Medical, LiveData, IBM, Philips, GE, and Datascope) and Partners HealthCare Information Systems have agreed to contribute equipment and engineering help, but additional funding will be needed to hire engineers to staff the Lab.

The web of collaborations for the MD PnP program began with the TATRC-sponsored May 2004 symposium and has continued to grow as a result of the June 2005 MD PnP symposium. These collaborations include activities and relationships with Federal agencies; clinical, engineering, and IT societies; clinicians in the USA, Europe, and Japan; and integrated health delivery networks.

Collaboration Highlights:

- The Society for Technology in Anesthesia (STA) stated their ongoing official support of the work and created an MD PnP working group that met with us for three hours at the

STA annual meeting in January 2006 to review the clinical use case scenarios compiled during the past year and to add additional requirements where needed.

- The US FDA/CDRH has committed a resource to provide guidance on strategic planning for the program, methodology for interpreting user requirements, and guidance for implementing the MD PnP Lab.
- On the recommendation of Gen. Eric Schoomaker of TATRC, the PI met with Dr. Fred Pearce at Walter Reed Medical Center to discuss potential synergies between the MD PnP work and the LSTAT program. This was synergistic with a meeting with Dr. Jose Salinas at the U.S. Army Institute of Surgical Research at Brooke Army Medical Center. These discussions included the possibility of a CRADA to facilitate future collaboration.
- Connections made at HIMSS with Dr. David Brailer and Dr. John Loonsk of the National Health IT Coordinator's Office led to subsequent meetings, enabling the PI to initiate a dialogue about the role of the MD PnP program in supporting the national health IT agenda.
- The National Institute of Standards and Technology invited the PI to participate in a workshop on "Open ICT Ecosystems for Healthcare," leading to several important new contacts.
- The National Science Foundation funded a plus-up to one of their grantees (University of Pennsylvania) working on modeling the safety of embedded software in medical devices, to collaborate with the MD PnP program.
- Kaiser Permanente is including language in its new contracts requiring medical device interoperability and referring to our MD PnP program, and is also assisting with the analysis of clinical use cases and providing strategic planning guidance.
- Connections made with IEEE and the American College of Clinical Engineering (ACCE) at the February 2005 HIMSS meeting resulted in attendance by both of these groups at the June symposium, and the PI was invited to attend the kick-off meeting in September of the Patient Care Medical Device domain group initiated by representatives of IEEE and ACCE under the auspices of IHE. Outcomes of this collaboration include interest on the part of this group in utilizing the MD PnP Lab as the site for ongoing testing of medical devices against standards, and provision of clinical use cases from the MD PnP program to the IHE.

These collaborations and many others have fed an ever-expanding support network for MD PnP, increasing the likelihood of program success.

The MD PnP web site (www.mdpnp.org, formerly www.orfpnp.org) continues to serve as a vehicle for communication and discussion forums for the program. The email distribution list for program communication expands as a result of each plenary meeting and word-of-mouth, and has grown to more than 415 names.

Key Research Accomplishments

- Increased the momentum of the MD PnP program by further increasing the diverse, committed stakeholder community
- Made excellent progress in refining the high-level clinical requirements elicited from anesthesiologists, surgeons, and clinical engineers
- Maintained a close working relationship with FDA that involves frequent interaction and committed participation in this effort
- Expanded collaborations with NSF, NIST, and University of Pennsylvania to include Draper Lab, Intel, and others, to enhance the quality and effectiveness of MD PnP subprojects, especially use case implementation in the Lab.
- Developed a clear vision and scope for the concept of a vendor-neutral laboratory, and progressed towards implementation of a prototype MD PnP Lab in calendar Q2 2006.

- Initiated high-level dialogue regarding the relationship of medical device interoperability to the national health IT agenda.

Reportable Outcomes

Meetings:

- August 2005 Clinical Requirements working group at IBM (7 participants)
- January 2006 MD PnP working group at STA (45 attendees)

MD PnP Presentations:

- June 2005 at Human Factors conference sponsored by Association for the Advancement of Medical Instrumentation (AAMI)
- July 2005 at Vanderbilt Medical Center
- July 2005 at CIMIT ORF course
- October 2005 at CIMIT Annual Briefing
- November 2005 at AdvaMed Software Conference, Washington DC
- January 2006 at STA annual meeting, MD PnP working group
- January 2006 "R.W. Virtue Lectureship" at University of Colorado
- February 2006 at "Real-Time GENI" workshop (NSF)
- February 2006 at HIMSS to ACCE
- February 2006 at HIMSS to LiveData workshop
- February 2006 at CIMIT ORF course
- February 2006 at University of Arizona Grand Rounds, Tucson
- March 2006 at MIT "M Language" workshop
- March 2006 at NIST "Open ICT Ecosystems" workshop
- March 2006 at University of Washington Grand Rounds, Seattle
- March 2006 at International Anesthesia Research Society annual meeting

Web Sites:

- www.mdpnp.org (formerly www.orfpnp.org) maintained as major communication vehicle
- Online interactive project planning site for working group on x-ray / ventilator lab demonstration project

Manuscripts/Publications:

- *24x7mag.com:* Section on "The Interoperability Payoff", based on Interview with Julian Goldman, in article on RFID, October 2005
- *Mass High Tech*: Interview with Julian Goldman *re* MD PnP Program, November 2005.
- Goldman JM, Jackson JL, Whitehead SF, Rausch TL, Weininger S, "The Medical Device 'Plug-and-Play' (MD PnP) Interoperability Program," part of Schrenker RA, "Software Engineering for Future Healthcare and Clinical Systems," *IEEE Computer,* April 2006.
- Goldman JM, "Medical Device Connectivity for Improving Safety and Efficiency," *American Society of Anesthesiology Newsletter* 70:5, May 2006. http://www.asahq.org/Newsletters/2006/05-06/goldman05_06.html

Funding Applications:

- Funded: CIMIT: $77K for FY06 core support of the Principal Investigator (12%) and Project Manager (25%)
- Funded: DoD: SBIR Phase II extension for LiveData grant, to support application of their work to PnP Lab
- Award expected in May 2006: TATRC BAA, $249K for 1 year for core program support for the PI (35%) and Project Manager (25%)

- Submitted: Partners Healthcare IS Research Council: $74.5K for Developing Formal Requirements-Engineering Methodology in Support of the MD PnP Program
- Submitted: CIMIT: $76K for FY07 for core support of the Principal Investigator (12%) and Project Manager (25%); jointly with Draper Lab, $75K for FY07 for clinical scenario modeling and systems engineering for the PnP Lab architecture

Other:

- In-kind engineering support and contribution of equipment for the lab from Draeger Medical, FDA, Draper Laboratory, Kaiser Permanente, and LiveData, and commitments from several other companies.

Conclusions

This second MD PnP symposium supported by TATRC and CIMIT built on the work from the previous year to leverage effective advancement of the MD PnP program towards developing a standardization framework for medical device interoperability. Significant progress was made in the areas of clinical requirements for MD PnP and development of a vision and plan for an MD PnP "sandbox" laboratory. The network of collaborators and stakeholders continues to expand, further confirming the relevance of the work, and concrete activities related to clinical scenarios and the MD PnP Lab have begun.

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1. "Plug and Play" Connectivity Initiative Launched, *AAMI News* 40:1, January 2005 (Association for the Advancement of Medical Instrumentation).
2. Goldman JM, Schrenker RA, Jackson JL, Whitehead SF. Plug-and-Play in the Operating Room of the Future. *Biomedical Instrumentation & Technology* 39:3, May/June 2005.
3. Brady J. Inside the OR of the Future. *Biomedical Instrumentation & Technology* 39:3, May/June 2005.
4. Wiley G, "The Interoperability Payoff", based on interview with Julian Goldman, sidebar of "The Search Is Over" (article on RFID), *24x7mag.com*, October 2005.
5. Hendrickson D, "Rx for the OR: Mass. Physicians tap experience and tech leaders to bring better medical solutions to market" (interview with Julian Goldman *re* MD PnP Program), *Mass High Tech*, November 2005.
6. Goldman JM, Jackson JL, Whitehead SF, Rausch TL, Weininger S, "The Medical Device 'Plug-and-Play' (MD PnP) Interoperability Program," part of Schrenker RA, "Software Engineering for Future Healthcare and Clinical Systems," *IEEE Computer,* April 2006.
7. Goldman JM, "Medical Device Connectivity for Improving Safety and Efficiency," *American Society of Anesthesiology Newsletter* 70:5, May 2006. http://www.asahq.org/Newsletters/2006/05-06/goldman05_06.html

Appendices

June Symposium Agenda
June Symposium Roster by Institution/Organization
MD PnP Lab Vision and Scope
IEEE Computer Article with PnP sidebar
ASA Newsletter MD PnP Article

June 6-7, 2005

Third Meeting of the ORF PnP Standardization Program

A multidisciplinary program to develop standards for communication and control of medical devices in the OR of the Future to improve patient safety and healthcare efficiency

Sponsored by: **CIMIT & TATRC**
Hotel@MIT, 20 Sidney Street, Cambridge, MA

Monday, June 6

8:00 – 9:00am	Registration / Continental Breakfast

9:00 – 9:15am	Welcome from CIMIT and TATRC *John A. Parrish, MD* Director, Center for the Integration of Medicine & Innovative Technology (CIMIT) *Ronald Marchessault, MBA* U.S. Army Telemedicine & Advanced Technology Research Center (TATRC)
9: 15 – 10:00	Conference Overview Year 1 Activities of ORF PnP Standardization Program *Julian M. Goldman, MD* Principal Investigator, ORF PnP Program CIMIT/Massachusetts General Hospital
10:00 – 10:15	The HCMDSS Connection (High Confidence Medical Device Software & Systems) – Report from the June 2-3 Workshop *Insup Lee, PhD* Director, Systems Design Research Lab Department of Computer and Information Science School of Engineering & Applied Science University of Pennsylvania
10:15 – 10:35	0R2020: Final Report from the March 2004 Workshop *Kevin Cleary, PhD* Deputy Director, Imaging Science & Information Systems Center Department of Radiology Georgetown University Medical Center
10:35 – 10:45	Break

Monday, June 6 (continued)

10:45am – 12:15pm WG1: Clinical Requirements for PnP in the ORF

Results of Clinical Requirements Focus Groups:
Society for Technology in Anesthesia (STA) – January 13
Julian M. Goldman, MD

Society of American Gastrointestinal Endoscopic Surgeons (SAGES) – April 15
Marc Shapiro, Olympus America Inc.

Additional Medical Forums
Julian M. Goldman, MD

Examples of Clinical Use Cases Beyond the OR
Kaiser Permanente

Association for the Advancement of Medical Instrumentation (AAMI) – May 14
Jennifer Jackson, MBA, Biomedical Engineering
Brigham & Women's Hospital

Extracting Engineering Requirements from Clinical Use Cases
Jim DelloStritto
Protocol/Welch-Allyn

12:15 – 1:15pm Networking Lunch Buffet (find someone interesting to sit with!)

1:15 – 2:00pm Vision for a PnP Laboratory
Julian M. Goldman, MD
Sandy Weininger, FDA
Jeff Robbins, LiveData Inc.

Experience at the University of New Hampshire InterOperability Lab
Gerard (Gerry) Nadeau, Manager, UNH-IOL

2:00 – 2:10 Instructions for breakout sessions
Julian M. Goldman, MD

2:10 – 2:15 Move into groups

2:15 – 4:00 **Breakout Session 1:** Clinical Requirements → Engineering Requirements
Review, refine, add new clinical input, develop implementation plan to hand off to WG3
Facilitators: Julian M. Goldman, and Sandy Weininger, FDA
Scribe: Bridget Moorman, Kaiser Permanente

Monday, June 6 (continued)

2:15 – 4:00pm	**Breakout Session 2:** Shaping the Vision of the PnP Lab *Facilitator: Jeff Robbins,* LiveData Inc. *Scribe: Rick Schrenker,* Biomedical Engineering Massachusetts General Hospital
4:00 – 5:30	Groups Report Back Identify Next Steps *Facilitator: Bill Joiner*

5:30 and 6:30pm	**Reception and Dinner** *Dinner Speaker: Warren M. Zapol, MD* Reginald Jenny Professor and Chairman, Department of Anesthesia and Critical Care, Massachusetts General Hospital

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Tuesday, June 7

7:00 – 8:00am	Continental Breakfast

8:00 – 8:10am	Introduction to Day #2
8:10 – 8:40	**WG2: Regulatory** *Jennifer A. Henderson, JD, MPH,* CIMIT
8:40 – 9:10	Investigating the PnP Value Proposition *Davis Bu, MD,* C!TL, and *Michael Robkin,* Kaiser Permanente
9:10 – 9:30	IHE Point-of-Care Medical Device Initiative *Ray Zambuto* Past President, American College of Clinical Engineering IEEE 1073 General Committee
9:30 – 9:45	Break
9:45 – 11:00	Introduction to PnP Lab Demos *Julian M. Goldman, MD* *Jeff Robbins,* LiveData Inc. *Jim DelloStritto,* Protocol/Welch-Allyn *Sebastien Cadet,* World of Medicine *Others TBA*

11:00am – 1:30pm	**PnP Lab Demos & Lunch** *Attendees will form 3-4 smaller groups to network and view demos at hotel and at CIMIT Simulation Center (2 blocks away) – buffet lunch will be provided and available at hotel during this period.*

Tuesday, June 7 (continued)

1:30 – 3:00pm	Discussion of Proposed PnP Lab Projects *Julian M. Goldman, MD* Model for Engaging Industry *Abe Abramovich* Director, Advanced Technology Datascope Corporation Long-Term Funding Strategy for the ORF PnP Program – What Should the Model Be? *Jennifer Jackson, MBA, and Julian M. Goldman, MD* Next Steps *Julian M. Goldman, MD*
3:00 – 3:15	Break
3:15 – 5:00	**WG3: Communication Architecture** *Chaired by Bill Seitz, IXXAT Inc., and Jeff Robbins, LiveData Inc.* *Scribe: Jennifer Jackson* *Facilitator: Bill Joiner* Group input on development of architectural roadmap
5:00pm	**Adjourn**

June 2005 PnP Standards: Attendees

By Institution/Company

Institution/ Company	Name	Email
American College of Clinical Engineering	Zambuto, Ray	rzambuto@techmed.com
ACIST Medical Systems, Inc.	Lafayette, Gregg	gregg.lafayette@acistmedical.com
	Maiers, Manfred	manfred.maiers@acistmedical.com
Brigham & Women's Hospital	Daniel, Ernst	edaniel@partners.org
	Feldman, Charles	CLFeldman@earthlink.net
	Jackson, Jennifer	jljackson@partners.org
CAN in Automation	Menon, Cyrilla	menon@can-cia.org
ChangeWise, Inc.	Joiner, Bill	bj@changewise.biz
CIMIT	Brown, Beverly	bbrown9@partners.org
	Crosby, Janice	jecrosby@partners.org
	Henderson, Jennifer	jahenderson@partners.org
	Humphrey, Ann	ahumphrey@partners.org
	Parrish, John	japarrish@partners.org
	Whitehead, Susan	swhitehead@partners.org
Cisco Systems, Inc.	Lohmann, Andrew	lohmann@cisco.com
Datascope Corporation	Abramovich, Abe	abe_abramovich@datascope.com
	Eaton, Scott	scott_eaton@datascope.com
	Fidacaro, Jim	jim_fidacaro@datascope.com
	Parsons, Samuel	sparsons@datascope.com
Draeger Medical Systems, Inc.	Clark, Robert	clarkr@draegermed.com
	Fuchs, Ken	ken.fuchs@draeger.com
	Wallroth, Carl	Beate.Moeller@draeger.com
Duke University Medical Center	Weitzner, Stanley	weitz001@mc.duke.edu
EQ International	Juett, Steve	sjuett@eqintl.com
FDA	Husband, Michael	MJH@CDRH.FDA.GOV
	Weininger, Sandy	sxw@cdrh.fda.gov
GE Healthcare Technologies	Schluter, Paul	Paul.Schluter@med.ge.com
	Seidl, Neal	neal.seidl@med.ge.com
Georgetown University Medical Center	Cleary, Kevin	cleary@georgetown.edu
Harvard University	Hedley-Whyte, John	john_hedley-whyte@hms.harvard.edu
	Milamed, Debra	debra_milamed@hms.harvard.edu
IBM	Perrera, Chris	perrera@us.ibm.com
IBM TJ Watson Research Center	Williams, Rose	rosemw@us.ibm.com
IEEE	Cooper, Todd	t.cooper@ieee.org
iMDsoft	Shefi, Moshe	moshe.shefi@imd-soft.com
IXXAT Automation GmbH.	Schlegel, Christian	schlegel@ixxat.de
IXXAT, Inc.	Seitz, Bill	seitz@ixxat.com

June Attendees Roster

Kaiser Permanente	Howse, John	JHowse6540@aol.com
	Judd, Thomas	tom.judd@kp.org
	Moorman, Bridget	bridget.moorman@kp.org
	Morris, Robert	robert.j.morris@kp.org
	Rausch, Tracy	tracy.rausch@kp.org
	Robertson, Scott	scott.m.robertson@kp.org
	Robkin, Michael	Michael.B.Robkin@kp.org
	Snyder, Bob	BobSnyder400@aol.com
	Wang, Jing	jing.m.wang@kp.org
LiveData, Inc.	Brzezinski, Philip	pbrzezinski@earthlink.net
	Cohen, Brett	bcohen@livedata.com
	Cullinane, John	john@cullinane-group.com
	Hughes, Kevin	kevinh@livedata.com
	Robbins, Jeffrey	jeffr@livedata.com
Lockheed Martin	Barton, Douglas	douglas.e.barton@lmco.com
Massachusetts General Hospital	Berman, Jesse	jberman@partners.org
	Goldman, Julian	jmgoldman@partners.org
	Sandberg, Warren	wsandberg@partners.org
	Schrenker, Rick	raschrenker@partners.org
Medtronic Emergency Response System	Peterson, Ken	ken.peterson@medtronic.com
MIT - AutoID Lab	Mun, In	ikm1@MIT.EDU
New York Presbyterian Hospital	Deland, Emme	eld9009@nyp.org
	Fowler, Dennis	dlf2001@nyp.org
	Milsom, Jeffrey	jwm2001@med.cornell.edu
	Mirsky, Michael	mim9026@nyp.org
	Riina, Howard	har9005@med.cornell.edu
	Suberman, Abbie	abs9008@nyp.org
Olympus America, Inc.	Masuda, Hiroshi	laureen.bufalo@olympus.com
	Mino, Hiroyuki	hiroyuki.mino@olympus.com
	Shapiro, Marc	marc.shapiro@olympus.com
Partners HealthCare	Bu, Davis	dbu@partners.org
	Vasios, George	georgevasios@comcast.net
Philips Medical Systems, Inc.	Harrington, Jack	jack.harrington@philips.com
	Weisner, Steve	steve.weisner@philips.com
	Wittenber, Jan	jan.wittenber@philips.com
Sg2	Maji, Catherine	clmaji@sg2.com
	Venkatraman, Giri	giri_venkatraman@yahoo.com
Smith & Nephew Endoscopy	Reed, Howard	Howard.Reed@Smith-Nephew.com
Stryker	Malackowski, Don	don.malackowski@stryker.com
	Wildgen, Mike	mike.wildgen@stryker.com
Tyco Healthcare, Inc.	Zanetti, Richard	Richard.Zanetti@tycohealthcare.com
University of New Hampshire InterOperability Lab	Nadeau, Gerard (Gerry)	grn@iol.unh.edu
University of Pennsylvania	Lee, Insup	lee@central.cis.upenn.edu

June Attendees Roster

U.S. Army Telemedicine & Advanced Technology Research Center	Marchessault, Ron	marchessault@TATRC.ORG
Vanderbilt University Medical Center	Patel, Nimesh St. Jacques, Paul	nimesh.patel@vanderbilt.edu paul.stjacques@vanderbilt.edu
Welch Allyn Inc.	DelloStritto, Jim	DelloStrittoJ@welchallyn.com
World of Medicine USA, Inc.	Cadet, Sebastien	sebastien.cadet@womcorp.com

Medical Device Plug-and-Play (MD PnP) Interoperability Program

at Massachusetts General Hospital and CIMIT

MD PnP Laboratory Vision & Scope

High-acuity healthcare remains complex and potentially dangerous, in part because clinicians depend on teamwork and a patchwork of systems to mitigate hazards instead of using integrated “error resistant” safety systems and automated decision support. As a result of the lack of medical device interoperability, many self-evident improvements in data communication (e.g. shared and centralized information), device integration, and human factors have not been achieved, and patient safety and economic benefits not realized. Without medical device interoperability, goals of remote device control and closed-loop control systems cannot be attained. The Medical Device Plug-and-Play program was initiated to remove the barriers to implementing comprehensive clinical interoperability solutions that will facilitate the widespread clinical use of medical device data and network-based medical device control. These barriers include the absence of validated interoperability standards and specific clinical requirements, and legal and regulatory concerns.

We are creating a vendor-neutral MD PnP Lab “sandbox” populated with medical devices that will serve as the focal point of the MD PnP program. The MD PnP Lab will be used to demonstrate and assess clinical examples of interoperability-based safety solutions, beginning with intra-operative care. Our experience implementing the Operating Room of the Future at Massachusetts General Hospital (MGH) will inform this process. During the past year, we elicited clinical scenarios from over 200 clinicians and clinical engineers at multiple meetings throughout the United States to identify examples in which the deployment of medical device interoperability standards could improve patient safety and healthcare efficiency in the perioperative environment. Selected “high-level clinical use-cases” will be implemented in the MD PnP Lab in order to study their potential clinical utility and to inform the selection, development, and implementation of candidate interoperability standards. Once vetted, candidate standards will be incorporated into an “MD PnP standardization framework” that will serve as an umbrella standard for medical device interoperability.

We will continue to draw on clinical resources to assure that clinical requirements remain the foundation of the derived technical specifications, and plan to coordinate the work with the Integrating the Healthcare Enterprise (IHE) program of the Health Information and Management Systems Society (HIMSS) to support cross-domain interoperability.

The MD PnP Lab must meet the challenge of networking currently available medical devices that do not use standardized network and communication interfaces, in order to create an appropriate development environment to (1) evaluate clinical scenarios, (2) investigate the performance of candidate medical device interoperability standards, (3) develop reference implementations of selected standards that are optimized for medical device PnP environments, and (4) document the benefits and limitations with respect to clinical and technical requirements. Fortunately, a vendor that has successfully deployed a system with the capability of networking disparate non-standardized devices in the OR of the Future has volunteered resources to deploy that system in the MD PnP Lab. This example of a non-standardized networked environment will provide a platform for rapid prototyping of standards-based solutions. Other vendors and governmental agencies have committed to support the Lab with donations of medical devices and engineering support.

The national impetus to improve Healthcare IT has been accelerated through bi-partisan support from the Executive and Legislative branches of government. The broad appeal of the MD PnP program is due in part to the alignment of its goals with pent-up national healthcare demands for interoperability. The MD PnP Lab will support the national health IT initiative by leveraging the consensus model of the MD PnP Program (with diverse clinical, vendor, and governmental involvement – including the FDA and DoD) to encourage broad stakeholder involvement and lead the adoption of interoperability solutions. We expect the MD PnP Lab to evolve into a national resource for Medical Device Interoperability and Patient Safety for the design, evaluation, and implementation of interoperable systems.

Julian M. Goldman, MD
MD PnP Program Director
Massachusetts General Hospital, Boston, MA
jmgoldman@partners.org
Mobile 617-827-2950
www.mdpnp.org

Sue Whitehead
Operations Manager / MD PnP Project Manager
Center for the **I**ntegration of **M**edicine & **I**nnovative **T**echnology (CIMIT)
65 Landsdowne Street, Suite 200, Cambridge, MA 02139
Office 617-768-8760, Fax 617-768-8770
swhitehead@partners.org

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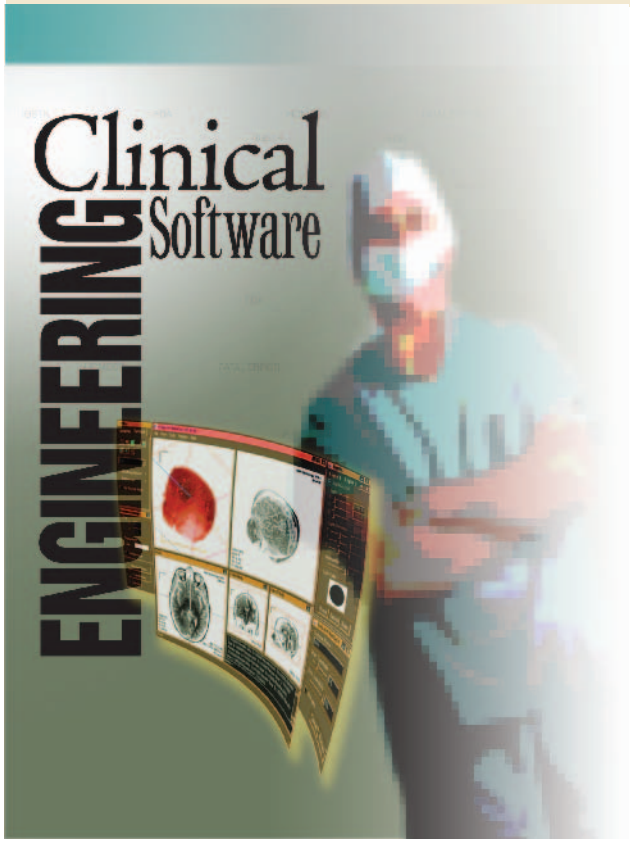

Software Engineering for Future Healthcare and Clinical Systems

Richard A. Schrenker
Massachusetts General Hospital

Systems and software engineering contribute not only to advancing and improving the delivery of healthcare but also to doing it more safely than has been the case in the past.

Turning "To err is human, but to really screw up, you need a computer" on its head, in 1999 the Institute of Medicine's *To Err Is Human: Building a Safer Health Care System* recommended[1] that healthcare professionals focusing on patient safety should increase their understanding of how information technology could be applied to deliver safer care. This recommendation was made as part of the approach to reducing errors in the delivery of care leading to the death of as many as 98,000 US citizens annually.

Much of the subsequent response to that challenge has focused on increasing the capabilities of enterprise hospital and clinical information systems—for example, implementing order-entry systems to check for drug allergies when writing prescriptions. But IT and patient care also come together at the bedside in the medical equipment and instrumentation systems used to deliver direct patient care—for example, smart infusion pumps that help ensure that the right dose of the right drug is administered to the right patient.

The articles in this special issue will touch on both types of systems, while focusing primarily on the application of software and systems engineering to software-based medical devices and device systems used at the bedside.

REVISITING THE PAST

There is no free lunch, of course. That software brings risks of its own to healthcare technology was not news in 1999. Six years before *To Err Is Human*, *Computer* published an evaluation of the Therac-25 accidents in which Nancy Leveson and Clark Turner provided what retrospectively may be seen as a "warning shot" regarding the impact of software on medical technology.[2] Under "Lessons Learned," they quoted a medical physicist:

> We have assumed … manufacturers have all kinds of safety design experience since they've been in the business a long time. We know that there are many safety codes, guides, and regulations to guide them and we have been reassured by the hitherto excellent record of these machines … Perhaps, though, we have been spoiled by this success.

The authors go on to note:

> If we assign software error as the cause of the Therac-25 accidents, we are forced to conclude that the only way to prevent such accidents in the future is to build perfect software that will never behave in an unexpected

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> or undesired way under any circumstances (which is clearly impossible) or not to use software at all in these types of systems.

They also note that "Although using good software engineering practices will not prevent all software errors, it is certainly required as a minimum" and that "Safety is a quality of the system in which the software is used; it is not a quality of the software itself."

These warnings echo in the enterprise domain as well. In "Some Unintended Consequences of Information Technology in Health Care: The Nature of Patient Care Information System-Related Errors," Joan Ash and colleagues cite examples of PCIS failures that led to decreased safety, the opposite intent of its design.[3] They recommend that "developers and vendors should be clearer about the limitations of their technologies."

Clinical demands appear to point to the need for a less linear and more collaborative process among manufacturers, regulators, and medical equipment users.

That said, today's limitations may have been yesterday's advanced features. Given the increasing rate of change of technological innovation and its introduction into healthcare delivery, it is not surprising to find different vintages of similar systems simultaneously available in clinical practice. This in turn can lead to originally unanticipated user expectations being applied to older systems, potentially resulting in unintended consequences not only in their application but also for developers, as described in the "Healthcare Professionals' Perceptions of Medical Software and What to Do About It" sidebar by Phillip A. Laplante and coauthors.

A similar problem is reflected at the point of delivery of care, where an increasing number of medical devices are embedded systems with complexity and capabilities that exceed products from just a few years ago.

Providing care to any one patient is likely to require multiple devices, particularly for the more acutely ill. The instrumentation at an intensive care bedside will minimally include a physiologic monitoring system to acquire, process, communicate, display, and generate appropriate alarms for ECG, one or more blood pressure devices, and devices for monitoring oxygen saturation, cardiac output, respiration, and other key parameters. Other devices likely to be in use will include infusion pumps (smart or otherwise) and a ventilator. Equipment that can be brought in as needed includes dialysis systems and laboratory equipment such as automated blood and chemistry analyzers.

Some patients will need all of the above and perhaps more; others will present different needs. Assuring the readiness and availability of this equipment requires having a robust and reliable medical technology management system.

CHALLENGES AHEAD

Responding to the demands of the patient care environment requires (among other things) hospital medical equipment inventories that are not only well-stocked—we currently manage more than 18,000 devices for our approximately 1,000-bed hospital—but fairly dynamic as well. New equipment—and new makes, types, and models of equipment—is added continuously, often replacing outdated equipment, but sometimes providing new functionality. Consequent human factors as well as technical and user training issues require ongoing monitoring and attention.

None of this is terribly new, but the addition of software-based medical devices adds more wrinkles. Henry Petroski's[4] admonition is worth remembering:

> Any design change … can introduce new failure modes or bring into play latent failure modes. Thus it follows that any design change, no matter how seemingly benign or beneficial, must be analyzed with the objectives of the original design in mind.

Managing software versions, installing patches, or placing devices on shared network infrastructures are examples of activities that are already introducing new sets of problems to the clinical environment, including some that have yet to manifest themselves.

Manufacturers, regulators—for example, the FDA—and medical equipment users all have played roles in the evolution of medical technology management systems that have brought us to this point. Viewing the process from 30,000 feet, manufacturers develop a device; regulators approve it for sale; and users buy, use, and maintain it. But it is not clear whether this model will remain sustainable going forward, as clinical demands driving technological responses appear to point to the need for a less linear and more collaborative process among the involved parties. For example, currently there is little in the way of standards-based interoperability among medical devices, even in the presence of ongoing efforts like IEEE 11073, which date back to the early 1990s.

Why these efforts have yet to succeed is not fully clear even to those of us who have been involved. However, over the past few years, a movement has started to take shape that is characterized not only by increased collaboration, but also by users taking a more active role in establishing the vision for future systems and deriving the requirements to which manufacturers and regulators need to respond.

Active efforts following this model include the creation of the American College of Clinical Engineering-sponsored Domain for Patient Care Devices within the Integrating

the Healthcare Enterprise Initiative (IHE PCD),[5] in which the collaborators include clinicians, engineers, and informaticists from healthcare providers as well as federal regulatory staff, manufacturers, and standards experts. Another derives from work started in the Massachusetts General Hospital's Operating Room of the Future[6] and is described by Julian Goldman and coauthors in their "The Medical Device 'Plug-and-Play' (MD PnP) Interoperability Program " sidebar.

BROAD VISION, NATIONAL AGENDA

Much like the fable of the blind men describing an

Healthcare Professionals' Perceptions of Medical Software and What to Do About It

Phillip A. Laplante, Colin J. Neill, and Raghvinder Sangwan
Penn State University

A March 2005 article by Ross Koppel and colleagues in the *Journal of the American Medical Association* exemplifies a sequence of reports highly critical of various kinds of medical informatics systems.[1] In this case, a *computerized physician order entry system* deployed at the University of Pennsylvania Medical Center came under fire. The article concluded that, contrary to conventional belief, a CPOE system might actually increase the number of medication errors as compared to a manual, handwritten system.

As faculty working at a graduate center with the mission of advancing the profession of software engineering, we were aghast at the implications (accusations, really) of the study reported in this article—that the software engineering employed in the development of this system was deficient or delinquent and was therefore an indication that our discipline is itself lacking. Particularly disconcerting was how the mainstream media picked up the article and further promoted the notion that software engineers were failing the medical profession.

Physicians' Perceptions of Software Engineering Practices

The Eclipsys CPOE system scrutinized in this study apparently was deployed from 1997 until 2004. When we contacted them, Eclipsys employees confirmed that because it had screens that were "usually monochromatic with pre-Windows interfaces," this was probably an older-generation system.

In any case, the conclusions drawn in the *JAMA* article about CPOE system design can be stated as follows:

- Focus primarily on the organization of the work, not on technology.
- Aggressively examine the technology in use.
- Aggressively fix technology when it is shown to be counterproductive.
- Pursue errors' "second stories" and multiple causations to surmount barriers enhanced by episodic and incomplete error reporting.
- Plan for continuous revisions and quality improvement, recognizing that all changes generate new error risks.

These are logical recommendations to derive from the study of a legacy system clearly developed with outmoded methodologies and technologies. Unfortunately, the study's authors chose to impute these findings on every CPOE system and neglected to mention the aged nature of this particular application—a fact that also was not noted by any of the media outlets that further promulgated the study's assertions.

To the further discredit of the software engineering profession, this study focused on the perceptions of system users who were unlikely to accept blame for their own errors or acknowledge their own inadequacies with respect to using the system. When the option is to accept fault yourself or to blame your tools, which would you choose?

The State of the Art?

We accept that in the past the industry has been sullied by well-publicized disasters caused by poorly designed medical software systems, most notably the Therac-25 debacle.[2] But it is incumbent on the software engineering profession to both publicize the advances that have been made in the past decade and to actively apply those advances.

For example, because the Eclipsys CPOE system was designed more than a decade ago, its developers most likely employed a waterfall life-cycle model. That the system failed to match the user community's needs and workflow is, therefore, no surprise.[3]

Numerous advances in software engineering have thoroughly addressed the software deficiencies that the critics of these medical software systems discovered. These advances include the growth of the subdisciplines of requirements engineering (focused on the gathering, documentation, and analysis of user requirements), user-interface design (focused on the design and construction of intuitive and safe user interfaces), and usability engineering (focused on the study of ease of use and suitability for purpose).

In addition to an improved software engineering paradigm, others have identified the need for better embedded medical device user interfaces to reduce errors.[4] We believe that software engineers should focus more attention on the usability aspects of medical systems, whether they are embedded or not. The greatest risk in not doing so are the kinds of medical errors uncovered in studies that rightfully criticize the failure to adopt good software engineering practices. The less obvious risk, however, is that failure to address usability

elephant, our perception of the scope of the application of information technology to healthcare is largely influenced by where we encounter the system. Virtually all of us can relate to issues associated with medical data records management, making it easier to appreciate the Institute of Medicine's recommendations for enterprise-level and larger information systems. Although less visible to the public, visions are beginning to take shape that are also national in scope but more focused on technologies used in the direct provision of care.

In "High-Confidence Medical Device Software and Systems," Insup Lee and colleagues describe a national

issues degrades the overall confidence that medical professionals have in software solutions even when an appropriate software engineering process has been used for all other aspects of the system except the user interface.

Ironically, contemporary requirements engineering techniques include many of the investigatory techniques employed by physician-researchers who study medical systems. *Joint application development* employs focus groups of project stakeholders so that each involved party is represented in the requirements elicitation stage. *Use case analysis* employs user-scripted scenarios of interaction to ensure that the computer system enforces a workflow and mode of operation that reflects not only the policies and procedures that must be met, but also the ways of working that the users themselves favor. *Contextual inquiry and ethnography* involve user shadowing and observation so that the analysts and developers involved in constructing the information system have a sufficient understanding of the problem domain to ensure that the delivered application conforms with current practice where necessary and optimizes current practices where possible. Other techniques such as using *formal methods* address the issue of ensuring that the code is correct and behaves according to the rules that the healthcare professionals determine.

These innovations within the software engineering community have been developed, or have been more widely adopted, since the deployment of many of the medical systems that have come under criticism. These techniques ensure that the delivered system does all that the users want and need and that the correct checks and balances are in place so that human-machine interface flaws and information errors do not arise.

Finally, we observe that many clinical systems currently in use were created prior to the recent, dramatic changes in healthcare delivery. Integrated health networks with more complex workflows and a greater need for seamless movement of patient data on demand, anywhere within the network, have for the most part replaced free-standing hospitals, clinics, and group practices. Retrofitting yesterday's systems to meet today's needs can only result in a "solution" that falls short, as the *JAMA* study clearly demonstrates.

Software engineers have long known that extensive retrofitting causes software to age very rapidly. Considering what we do know about building complex software systems and in the light of these dramatic changes in the industry, it is unfortunate that the prevailing sentiment among healthcare professionals seems to be that legacy information systems, their developers, and their vendors are failing to meet the needs of physicians and hospitals.

Moving Forward

The message that should be delivered is that hospital administrators must push for modern computer systems rather than taking the cheap way out and trying to adapt outdated technology. Further, healthcare professionals have a role to play in the specification, validation, and deployment of complex software systems such as CPOE. The burden to deliver correct and usable applications isn't entirely on the software engineers and software vendors. Software engineering professionals must be proactive in educating healthcare professionals about the role they must play in building systems that are responsive to their needs and are reliable and safe.

As it turns out, several major medical systems developers—Eclipsys, Siemens Medical Solutions, and McKesson HBOC—are all located near our campus, and some of our best students hail from these companies. Therefore, we know that, whatever the state of affairs was 10 or 20 years ago, at least some representatives of the medical software community are now applying state-of-the-art software engineering techniques in the development of medical informatics systems—including design for usability.

As a profession, we must get the word out to healthcare providers that the state of affairs in software engineering has improved dramatically.

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Phillip A. Laplante *is an associate professor of software engineering at Penn State University. Contact him at plaplante@gv.psu.edu.*

Colin J. Neill *is an associate professor of software engineering at Penn State University. Contact him at cjn6@psu.edu.*

Raghvinder Sangwan *is an assistant professor of information science at Penn State University. Contact him at rxs69@psu.edu.*

collaborative effort involving academics and professionals working together to identify and address the critical issues presented by the emergence of intelligent clinical technologies.

Vision meets reality

Moving from vision to product requires not only attention to good software engineering practices and awareness of the regulatory environment, but also a grounding in fundamental risk management principles. Steven R. Rakitin explores all three in "Coping with Defective Software in Medical Devices."

Reality meets New Age: How can we not use agile methods?

In "IGSTK: An Open Source Software Toolkit for Image-Guided Surgery," Kevin Gary and colleagues start with a description of the critical requirements posed by the needs of image-guided surgery that, when coupled with the resources available to his team, result in daunting development constraints. The authors describe the development and application of a mixture of classical and agile tools and methods in support of their clinical application.

Wireless changes everything

In many institutions, it once was easy to partition medical and nonmedical networked devices by installing them on physically distinct wired networks. That degree of control effectively came to an end with the introduction of wireless medical device networks. In "Ensuring Patient Safety in Wireless Medical Device Networks," Vijay Gehlot and Elliot B. Sloane provide an insightful view into the risks, details, and nuances

The Medical Device "Plug-and-Play" (MD PnP) Interoperability Program

Julian M. Goldman, Massachusetts General Hospital
Jennifer L. Jackson, Brigham and Women's Hospital
Susan F. Whitehead, Center for the Integration of Medicine & Innovative Technology
Tracy L. Rausch, Kaiser Permanente Mid-Atlantic States
Sandy Weininger, FDA Center for Devices and Radiological Health/OSEL/DESE

A patient undergoing gallbladder surgery is under general anesthesia during the procedure. To avoid image blurring while taking X-ray images during the surgery, it is necessary to switch off the ventilator that is breathing for the anesthetized patient. Turning the ventilator off, taking the X-ray, and turning the ventilator back on again are all manual processes. If the team of caregivers is distracted, it is possible that the ventilator might not be turned back on. Although very unlikely, this tragedy has occurred (www.apsf.org/resource_center/newsletter/2004/winter/03turn_on.htm).

This scenario is one of many involving ensembles of stand-alone medical devices in which each acts as a stand-alone device, with its only sources of information coming from the operator and sensors. If the X-ray machine and ventilator were context-aware and able to communicate with one another, synchronization of the X-ray exposure to the phase of ventilation could minimize the need to turn off the ventilator, substantially reducing the potential for the disaster described above. The same approach could improve image quality and decrease wasted images and unnecessary X-ray exposure when X-rays are taken in the intensive care unit.

But the state of the art with respect to medical device interoperability is reflected in a small number of proprietary products that provide some capabilities geared primarily at populating patient record systems and single-vendor "integrated" networked systems. Despite almost 20 years of attempting to define standards that enable medical device interoperability, little real progress has been made in terms of delivering solutions to the market, particularly for problems involving emergent, real-time patient care.

The absence of market-ready interoperability solutions has stalled the development of fully integrated electronic health records, smart alarms, real-time clinical decision support systems, and automated safety systems (with medical device interlocks). As a result, clinicians cannot easily use technology to enhance situational awareness or control devices in the clinical environment, and they must continue to rely instead on teamwork and a patchwork of systems to mitigate clinical hazards.

Inspired by successes such as the Operating Room of the Future (ORF) program at Massachusetts General Hospital (MGH) and driven as much by frustration at not being able to provide the "latent opportunities" of innovation in clinical care that we know modern technology could support, as well as by the rapidly changing economics and dynamics of the patient care environment, we in the user community are beginning to respond.

In our case, we have established a program to fully address medical device interoperability to support the development of connected, error-resistant medical device systems throughout the continuum of healthcare. Over the past two years, the Medical Device Plug-and-Play Interoperability Program (MD PnP; www.mdpnp.org), founded by the Center for the Integration of Medicine and Innovative Technology (CIMIT; www.cimit.org/orfuture.html) and MGH, has surveyed clinical groups representing leading surgeons, anesthesiologists, nurses, and clinical engineers to acquire the information needed to derive use cases and drive requirements definitions. We are converting selected clinical use cases into pro-

of placing such a system into service. They also examine the subtleties driving the need for hospital-based clinical engineering involvement in system verification and validation.

Everything Changes FDA

Cognizant of issues like the ones that challenged Gary's team, regulators are faced with determining how to respond to issues that emerge with the rapid evolution of software-based medical devices. In "A Formal Methods Approach to Medical Device Review," Raoul Jetley and colleagues describe a set of formal approaches for application test and validation during the premarket approval process or when doing a forensic analysis of problems that occur after a device has been delivered to the market.

Indeed, to err *is* human. But it does not follow that harm cannot be prevented. Systems and software engineering contribute not only to advancing and improving the delivery of care but also to doing it more safely than has been the case in the past. Doing so appears likely to require greater collaboration between manufacturers, regulators, and users in the future. And it *is* happening.

But more needs to be done, and soon. While the work that the IHE and MD PnP are doing makes many of us hopeful that interoperable medical device systems will soon begin to be realized, hard questions need to be asked, such as, Why did IEEE 11073 move so slowly? What more needs to happen for its vision to be realized in the market? What could we do differently to avoid similar inertia when tackling future systems and software engineering problems?

totype models to be implemented in our MD PnP Lab with commercially available medical devices.

The MD PnP Lab is implementing the gallbladder imaging scenario as the first clinical use case around which to begin to define, select, or develop the processes, tools, framework, and components with which to construct the needed system. Throughout the MD PnP program, it is our intent to reuse and leverage existing work wherever possible, and we will support the use of currently existing consensus standards if they can contribute to the implementation of these clinical use cases. We are also acutely aware that other significant challenges, such as data security, liability and regulatory issues, network performance monitoring, and interoperability with the broader healthcare enterprise must also be addressed.

The impetus for the MD PnP program relies on both the visionary and real foundation provided by the ORF along with the collaboration and extended vision of its members. The ORF, a program of CIMIT and MGH, is a fully functioning OR suite in MGH. The ORF serves as a "living laboratory" for clinicians, engineers, technicians, architects, and administrators to study the impact of process change, technology, and teamwork on safety and productivity. The ORF also serves as a protected environment and aggregation point to develop and safely validate and test those ideas, including MD PnP, that are envisioned as necessary to lay the foundation for safety and efficiency innovations in perioperative healthcare.

The MD PnP "geographically dispersed team" includes not only members of Partners HealthCare clinical, information services, and clinical engineering staff but also colleagues from other integrated healthcare delivery networks (IHDNs) such as Kaiser Permanente; marketing and engineering staff from medical device manufacturers; FDA and NIST staff involved in the regulation and testing of software-based medical devices; marketing and engineering staff representing manufacturers of information technology-based hardware and software; and members of academic and research communities.

Many MD PnP members are also involved in efforts like IEEE 11073 and the Integrating the Healthcare Enterprise Initiative Domain for Patient Care Devices (IHE PCD) of the Healthcare Information and Management Systems Society. Opportunities to work together come both at the various standards meetings as well as on shared projects and problems.

The continued lack of automated safety systems, smart alarms, closed-loop control, and decision support systems at the patient bedside, coupled with the tacit acceptance of resultant risks that thereby accrue, is unconscionable in the presence of readily available technology that is applied to similar goals seemingly everywhere but healthcare. We in the MD PnP program are intent on addressing it.

***Julian M. Goldman, MD**, is the director of the Medical Device "Plug-and-Play" Interoperability Program in the Departments of Anesthesia and Biomedical Engineering at Massachusetts General Hospital and the Center for the Integration of Medicine and Innovative Technology. Contact him at jmgoldman@partners.org.*

***Jennifer L. Jackson** is the assistant director of biomedical engineering at the Brigham and Women's Hospital, Boston, Mass. Contact her at jljackson@partners.org.*

***Susan F. Whitehead** is the Medical Device "Plug-and-Play" Interoperability Program project manager in the Center for the Integration of Medicine & Innovative Technology, Cambridge, Mass. Contact her at swhitehead@partners.org.*

***Tracy L. Rausch** is a clinical systems engineer at Kaiser Permanente Mid-Atlantic States, Rockville, Md. Contact her at tracy.rausch@kp.org.*

***Sandy Weininger** is a senior regulatory engineer, FDA Center for Devices and Radiological Health/OSEL/DESE, Rockville, Md. Contact him at sandy.weininger@fda.hhs.gov.*

The involvement of experts from outside the medical technology domain could prove valuable. For example, researchers might be better positioned to help us more rigorously address emerging issues such as whether medical device networks should merge with hospital or other clinical information systems networks. And, jumping even further outside the box, consideration needs to be given to how healthcare-based engineers, caregivers, and technologists can become even more engaged in technology definition, development, and design decisions and activities, to, for example, address human factors issues that will likely increase with device and system complexity.

Medicine remains fundamentally reactive; we wonder how it can be otherwise. A person can do everything possible to remain healthy, but sooner or later, if an accident doesn't strike, illness will. When this occurs, clinicians attending to the patient remain driven by the basic principle, "First, do no harm," and they expect that the tools they use will not permit their violating that principle.

To address patient safety in the face of the perturbations that arise from human error as well as other sources, proactive systems and software engineering attention must increasingly focus on continuously creating robust, reliable, and dependable applications and an infrastructure focused on addressing needs at the point of delivery of care.

Acknowledgments

I thank Bob Colwell for encouraging me to serve as guest editor for this special issue and Scott Hamilton for patiently shepherding me through the process. I received appreciated feedback on this editorial from my colleagues Mike Cusack, Luis Melendez, and Jason Davis. The work and guidance of my colleague, patient-safety expert Jeff Cooper, has inspired my interest in relating software, systems, and clinical engineering around safety. Last and most, I want to jump outside the engineering box to thank my father, Dick Schrenker, for inspiring me to put first things first in whatever I do. Hence, the theme not just of this editorial but the application of technology wherever it touches medicine: When it comes to what engineering brings to healthcare, safety comes first.

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Richard A. Schrenker *manages the Systems Engineering Group in the Department of Biomedical Engineering at Massachusetts General Hospital. He received an MS in electrical engineering from Johns Hopkins University. Schrenker is a member of the IEEE EMBS and Computer Societies, the American College of Clinical Engineering, the ACM, and the Association for the Advancement of Medical Instrumentation, and is a cofounder and Life Member of the Baltimore Medical Engineers and Technicians Society. He is active in IEEE 11073, IHE PCD, and MD PnP development efforts. Contact him at raschrenker@partners.org.*

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Medical Device Connectivity for Improving Safety and Efficiency

Julian M. Goldman, M.D.
Committee on Electronic Media and Information Technology

"Use wireless technologies to eliminate the 'malignant spaghetti' of cable clutter that interferes with patient care, creates hazards for the clinical staff and delays positioning and transport."

"Synchronize the respiratory cycle of the anesthesia machine ventilator with portable X-ray exposure so that an X-ray will be triggered at end-expiration, thus avoiding the need to turn-off the ventilator for an intraoperative cholangiogram."

"Trigger the portable X-ray at end-inspiration by synchronizing with the ICU ventilator."

"Why can't a pulse oximeter be connected to a PCA infusion and automatically interrupt the infusion and activate an alarm when a patient is hypoxemic?"

"Support the recording of infusion pump data in the electronic anesthesia information system and permit control of the infusion rate at the anesthesia machine."

These are only a few examples of clinical scenarios provided by anesthesiologists to articulate their vision of improvements in clinical care that could be achieved by interconnecting medical devices.[1] The barriers to medical device connectivity (or "interoperability") are well known to those anesthesiologists and clinical engineers who have tried to install anesthesia information management systems (AIMS) or to interconnect devices and computers for clinical research. In contrast to the ubiquitous USB memory devices that support effortless connectivity on all brands and types of modern computers, or the Internet browser programs and Web sites that enable secure banking over the Internet, we have not implemented equivalent secure, ubiquitous connectivity technology to

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support vendor-neutral medical device networks. As a result, the cost and complexity of seamless connectivity is interfering with widespread deployment of AIMS, remote monitoring, use of comprehensive (laboratory + monitor) data to develop clinical decision support systems and smart alarms.

The importance of interoperability to support improvements in health care has been underscored by the establishment of the position of the National Health Information Technology (HIT) Coordinator on April 27, 2004, to provide leadership for the "development and nationwide implementation of an interoperable health information technology infrastructure to improve the quality and efficiency of health care."[2]

The vision includes developing "a nationwide interoperable health information technology infrastructure that:

> "2a. Ensures that appropriate information to guide medical decisions is available at the time and place of care;
>
> 2b. Improves health care quality, reduces medical errors and advances the delivery of appropriate evidence-based medical care;
>
> 2c. Reduces health care costs resulting from inefficiency, medical errors, inappropriate care and incomplete information; and
>
> 2d. Promotes a more effective marketplace, greater competition and increased choice through the wider availability of accurate information on health care costs, quality and outcomes."

Similarly the 2005 Institute of Medicine Report, *Building a Better Delivery System: A New Engineering /Health Care Partnership*, emphasizes the need for a National Health Information Infrastructure "to support the information-driven practice of contemporary medicine. This infrastructure would consist of standards for connectivity, system interoperability, data content and exchange, applications and laws."[3]

The absence of effective medical device connectivity has been due in part to an absence of implemented open standards, the lack of financial incentives for device manufacturers to provide systems to support vendor-independent connectivity, legal and regulatory concerns and unclear clinical specifications — or "clinical requirements" — for the proposed systems.

The national HIT agenda includes making the interoperability of electronic health care records (EHR) a reality, but we are concerned that EHRs will be neither complete nor accurate until the inclusion of medical device data is automated.

There are two distinct, and closely related, facets of medical device interoperability:

> • *Data communication* standards will support accurate data acquisition by the EHR from monitors, infusion pumps, ventilators, portable imaging systems and other hospital and home-based medical devices. Reliable data will support complete and accurate EHRs and robust databases for continued quality improvement

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use.

• *Medical device control* standards will permit the control of medical devices to produce "error-resistant" systems with safety interlocks between medical devices to decrease use errors, closed-loop systems to regulate the delivery of medication and fluids and remote patient management to support health care efficiency and safety (e.g., remote intensive care unit, management of infected/contaminated casualties).

The Medical Device Plug-and-Play (MD PnP) program was initiated in May 2004 at the Center for Integration of Medicine and Innovative Technology, or CIMIT, and Massachusetts General Hospital to identify and implement connectivity standards while ensuring that they remain clinically grounded **<www.mdpnp.org>**.[4, 5] The program has convened diverse stakeholders (clinicians, the Food and Drug Administration, manufacturers, biomedical and clinical engineers, clinical societies and others) to develop a roadmap for open-standards-based, vendor-neutral medical device interoperability. The early identification of the importance of basing interoperability solutions on clinical requirements led us to begin compiling the unique body of clinical requirements represented in the examples above. The clinical requirements were elicited from clinicians and engineers who were asked to provide examples of connectivity that could a) solve current clinical problems, b) improve safety or efficiency or c) enable innovative clinical systems of the future. A major goal is to identify potential solutions to perceived shortcomings of current clinical practice or ideas for future innovations that require improved interoperability for implementation. The MD PnP Lab, scheduled to open in the second quarter of 2006, provides a vendor-neutral environment in which to evaluate the feasibility of implementing some of these clinical scenarios, including evaluating connectivity products and standards as they are developed. The Lab thus provides the protected environment that will enable latent opportunities for improving patient safety to be explored and realized.

We will hold an open session at the ASA 2006 Annual Meeting in Chicago to gather *your* clinical requirements for inclusion in the master requirements list, which will guide national solutions. Feel free to get started now by sending your ideas to us at **<asa@mdpnp.org>** or posting your ideas and initiating discussion on the discussion area of **<www.mdpnp.org>** (free registration required to post information).

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Julian M. Goldman, M.D., is Assistant Anesthetist, Massachusetts General Hospital (MGH)/Harvard Medical School, Physician Advisor, Partners HealthCare Biomedical Engineering at Massachusetts General Hospital, Boston, Massachusetts, and Program Leader, CIMIT/MGH Medical Device "Plug-and-Play" Interoperability Program. He is President of the Society for Technology in Anesthesia.

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